

On the use of vaccines against COVID-19 in Iceland

*The dose interval used for vaccinations depends on the dose interval in pre-marketing vaccine studies. This applies to all types of vaccines. In general, there is a greater risk of decreased response to vaccination if the interval between doses is too short than if it is longer than the manufacturer recommends.

Pfizer/BioNTech:

- mRNA vaccine (genetic material in lipid particles, no virus).
 - The body reads the mRNA and produces proteins that the immune system learns to recognise.
- A. One-component vaccine with mRNA for the S protein of the original variant: **discontinued on** May 1, 2023
 - Must be mixed if appropriate, and all doses from the vial must be used immediately (within 6–12 hours).
 - People must be gathered together, but not too many; suitable all over the country.
 - Allergic reactions are more common than with some other vaccines.
 - Takes 3–6 weeks to complete vaccination; should not be delayed longer than 12 weeks.*
 - In some cases, vaccine must be reserved to ensure that there is an appropriate interval between vaccinations.
 - Suitable for use for those 5 years and older (note: different doses for 5–11 years of age or 12 years and older).
 - The first vaccine to become available in Iceland. Agreement in place on continued use in 2022–2023 with an updated vaccine. Used for:
 - The elderly and healthcare professionals who were the first to be vaccinated.
 - At-risk groups that needed complete vaccination quickly (e.g. due to delays in treatment in order to complete vaccination, such as cancer treatment, biotech drugs for rheumatism, etc.).
 - All individuals aged 5–17 years' old who choose to be vaccinated.
 - No other vaccine was registered for 16- to 17-year-olds until after the end of mass vaccinations.
 - It was decided to use this rather than the Moderna vaccine for those aged 12–15, partly due to the lower dose of vaccine in the Pfizer vaccine than Moderna.
 - No other vaccine had a marketing authorisation for 5- to 11year-olds when vaccinations began at the turn of the year 2021–2022.
 - Pregnant women (<u>see EMA's opinion pub. 8.12.2022</u>)
 - Others who need primary vaccination depending on the availability of vaccine.
 - Booster vaccinations irrespective of age until September 2022.

Three issues:

- 1. Unmixed for ages 12 and older:
 - 7 doses in a vial if the right equipment is available, otherwise 6.
 - Requires a special extremely cold freezer (-80°C) for long-term storage.
 - Store for 10 days in a refrigerator (unopened vial).
- 2. Unmixed for ages 5–11:
 - 12 doses in each vial if the right equipment is available, otherwise 10.
 - Store for 10 days in a refrigerator (unopened vial).
- 3. Pre-mixed for ages 12 and older:
 - 7 doses in a vial if the right equipment is available, otherwise 6.
 - Store for 10 days in a refrigerator (unopened vial).
- B. Two-component vaccine with mRNA for S proteins of the original variant and Omicron variant:
 - 7 doses in a vial if the right equipment is available, otherwise 6.
 - Requires a special extremely cold freezer (-80°C) for long-term storage.
 - Store for 10 days in a refrigerator (unopened vial).
 - Use:
 - additional and booster doses from September 2022.
 - primary vaccination plus booster from May 1, 2023.

Two versions:

- Original variant (WT) and Omicron BA.1 unmixed for ages 12 and older:
 Discontinued in December 2022 due to later version.
- 2. Original variant (WT) and Omicron BA.4/5 unmixed for ages 5 and older:
 - Usage began in December 2022.
 - Different doses for 5–11 years' old or 12 years and older.

Moderna:

- mRNA vaccine (genetic material in lipid particles, no virus).
 - The body reads the mRNA and produces proteins that the immune system learns to recognise.
- A. One-component vaccine with mRNA for the S protein of the original variant: **discontinued in November 2022.**
 - Must be kept in the dark during transport and storage.
 - 11 doses in each vial if the right equipment is available, otherwise 10.
 - Booster vaccination: 20–21 doses in each vial.
 - Comes pre-mixed, but all doses from the vial must be used immediately.

- People must be gathered for vaccination in rather large groups; best suited to urban areas.
- Allergic reactions are more common than with some other vaccines.
- Takes 4 weeks to complete primary vaccination; should not be delayed longer than 12 weeks.*
 - Doses might have to be reserved to ensure that there is an appropriate interval between vaccinations.
- Appropriate for use for 6 months' old and older, according to marketing licence. Due to the larger dose of vaccine than in the Pfizer vaccine, and the apparently higher frequency of side effects, the Pfizer vaccine is more recommended for everyone under 18 years of age.
- The incidence rate of carditis and pericarditis is higher in men aged 18–49 years than in other age groups and in women, especially after the second dose. Therefore, restrictions on the use of the vaccine in Iceland and elsewhere are recommended in October 2021.
- Allowed for pregnant women, but Pfizer is more recommended here in Iceland.
- The second vaccine to become available in Iceland.
 - Vaccinated before 8 October 2021:
 - Healthcare professionals and responders (police, etc.) first, mainly in urban areas.
 - At-risk groups that need complete vaccination quickly (e.g. due to delays in treatment to order to complete vaccination, such as biotech drug treatment, etc.), mainly in urban areas.
 - Others who need primary vaccination while the vaccine is available, including pregnant women.
 - Booster vaccinations after Janssen vaccination, third dose for immunosuppressed and elderly people in the capital area.
 - Vaccinated after 12 October 2021:
 - Booster vaccination for immunosuppressed individuals and people 60 years of age and older.
 - May be used to complete the vaccination of 18- to 59-year-old women and 40- to 59-year-old men who have received the Moderna vaccine and wish to complete the primary vaccination with the same vaccine. It is not recommended to give Moderna to men aged 18–39 years at present.
 - \circ ~ Vaccinated after 5 November 2021:
 - Booster vaccination for women from 18 years of age and men from 40 years of age.
- B. Two-component vaccine with mRNA for S proteins of the original variant and Omicron variant:
 - Must be kept in the dark during transport and storage.
 - 11 doses in each vial if the right equipment is available, otherwise 10.
 - Comes pre-mixed, but all doses from the vial must be used immediately.
 - People must be gathered for vaccination in rather large groups; best suited to urban areas.
 - Use:
 - additional and booster shots from September 2022, age limits acc. to A above.
 - primary vaccination from May 1, 2023, age limits acc. to A above.

Two versions:

- 1. Original variant (WT) and Omicron BA.1:
 - Discontinued in December 2022 due to later version.
- 2. Original variant (WT) and Omicron BA.4/5:
 - Usage began in December 2022.

Nuvaxovid: Usage discontinued on 1 January 2023:

- Contains the S protein of the original SARS-CoV-2 variant and a Matrix-M adjuvant. Rather traditional vaccine, comparable to annual influenza vaccines; however, the adjuvant is quite novel, produced from Soapbark trees and is considered less of an allergen than for example aluminium adjuvants.
- There are 10 doses in each vial, no mixing needed.
- Must be used within a few hours of opening the vial.
- Allergic reactions have an unknown frequency.
- Suitable for use by those 12 years' old and older. Suitable for individuals at risk of severe COVID-19 infection. Can be used for individuals with allergies for certain ingredients in mRNA vaccines, f. ex. PEGs, with the opinion of an immunologist.
- The fifth vaccine to become available in Iceland. Used for:
 - Primary vaccination for individuals who are allergic to mRNA vaccines or their ingredients, that do not have a known allergy to Nuvaxovid contents.
 - Primary vaccination for others that do not accept mRNA vaccines and request a twodose vaccine.
 - Booster vaccination for individuals who are advised against receiving mRNA vaccines, irrespective of what vaccine was used for the primary vaccination.

Janssen: Usage discontinued on 1 May 2023

- A cold virus (adenovirus 26) that has been inactivated so that it cannot reproduce and that has had genetic material added for the same protein as our bodies produce after mRNA vaccination.
- Transported frozen but can be stored at the vaccination site under the same conditions as the vaccines we use daily in the healthcare system.
- 5–7 doses in each vial.
 - Must be used within a few hours of opening the vial, but it does not need to be mixed and used immediately like the mRNA vaccines.
 - Can be well suited in rural areas and for individuals who are difficult to reach for vaccination due to residence, work or otherwise.
- Allergic reactions are not as common as with mRNA vaccines.
- Blood clots of the same type known with the AstraZeneca vaccine have occurred where millions of doses have been used but are extremely rare.
- One dose significantly reduces the risk of infection, serious illness and death from COVID-19 disease due to the original virus. Inadequate efficacy against infection and serious illness with Delta and Omicron variants. A booster dose with the same vaccine enhances the protection in a comparable way to two doses of the other vaccines, but here, an additional dose of an mRNA vaccine is recommended at least 4 weeks after Janssen vaccination, in addition to a booster dose a few months after the additional dose.

- Suitable for use by those 18 years and older. Suitable for individuals at risk of severe COVID-19 infection. Studies on the vaccination of children have begun, but agreements on the use of this vaccine have expired and other vaccines will be used for children here.
- The fourth vaccine to become available in Iceland. Used for:
 - At-risk groups that needed vaccination as soon as possible, although this vaccine is not recommended for severely immunosuppressed individuals or for pregnant women.
 - Individuals who might not be able to receive two doses in Iceland, such as individuals who work in Iceland but reside in a foreign country or work in a foreign country but reside in Iceland.
 - Those 18 years and older with a history of COVID-19 illness.
 - Others who are in need of vaccination until the vaccine runs out, according to a published Priority List.
 - From **18 January 2022**, use is primarily restricted to those who are allergic to mRNA vaccines, or if a doctor recommends adenovirus vector vaccines rather than other vaccines, whether for a primary vaccination or a booster one.
 - Since September 2022, only recommended for use in primary vaccination because of contraindication to mRNA vaccines. Authorised for booster vaccination, according to medical advice (not as broad spectrum as mRNA vaccines from September 2022).

AstraZeneca: Discontinued in November 2021:

- An ape cold virus that has been inactivated so that it cannot reproduce and genetic material added for the same protein as our bodies produce after mRNA vaccination.
- Transported and stored under the same conditions as the vaccines we use in routine primary care.
- 10–12 doses in each vial.
 - Must be used within a few hours of opening the vial, but it does not need to be mixed like the mRNA vaccines.
 - Can be quite suitable in rural areas, although quite a few people need to be vaccinated on the same day.
- Allergic reactions_are not as common as with mRNA vaccines.
- An unusual type of blood clot has been reported as a serious but rare side effect in many European countries, (varies by country, 1/23,000–100,000 doses), see further <u>here</u>.
- Takes 12 weeks to complete vaccination; interval can be shortened (down to as little as 4 weeks), but protection is better with a longer interval.*
 - No need to reserve vaccine to ensure specific intervals.
- Registered for individuals aged 18 and over. To begin with, there was uncertainty about efficacy in those aged 65 and older due to the small number of participants in that age group in pre-marketing <u>research</u>, but the data available is now adequate due to UK research, (see here and here). Suitable for individuals at risk of severe COVID-19 infection. Changes to the groups receiving this vaccine were made and then repeated due to unusual blood clots (see above). Research on vaccination for children has begun, but it is unlikely to be used for children in Iceland in the coming years.
- The third vaccine to become available in Iceland.
 - Vaccinated before 10 March 2021:
 - Nursing home staff, 18- to 64-year-olds.
 - At-risk groups who need to start vaccination as soon as possible but are not receiving treatment that affects the timing of the second dose, 18–64 years.
 - Healthcare professionals who have not already been vaccinated.
 - Vaccinated after 24 March 2021:

- Individuals 70 years and older who have not already been vaccinated (group 6 according to published Priority List).
- We are awaiting data on other low-risk groups, with regards to blood clots, before expanding vaccination to other groups.
- Vaccinated after 9 April 2021:
 - Individuals 60 years of age and older who have no history of spontaneous thrombus or diseases that increase the risk of phlebothrombosis.
- Vaccinated after 30 April 2021:
 - Women 55 years of age and older who have no history of spontaneous thrombus or certain diseases that increase the risk of phlebothrombosis.
 - Men who have no history of spontaneous thrombus or certain diseases that increase the risk of phlebothrombosis.
- Vaccinated after 12 May 2021:
 - Women born in 1966 or earlier who have no history of spontaneous thrombus or certain diseases that increase the risk of phlebothrombosis.
 - Men born in 1981 or earlier who have no history of spontaneous thrombus or certain diseases that increase the risk of phlebothrombosis.
 - Women born in 1967 or later and men born in 1982 or later who have already received a previous dose may request to be vaccinated with the same vaccine, although another vaccine is expected to be given.